PTO/SB/17 (1-06)
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2006

Patent fees are subject to annual revision.
Effective December 8, 2004

TOTAL AMOUNT OF PAYMENT ($)500

Complete if Known	
Application Number	10/090,517
Confirmation Number	6459
Filing Date	March 4, 2002
First Named Inventor	Bradley Steven Resch
Examiner Name	Shengjun Wang
Art Unit	1617
Attorney Docket No.	8866

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METHOD OF PAYMENT

1. [X] The Director is hereby authorized to charge indicated fees submitted on this form, credit any over payments, and charge any additional fee(s) during the pendency of this application to:

Deposit Account Number: 16-2480
Deposit Account Name: The Procter & Gamble Company

FEE CALCULATION

2. BASIC FILING FEE – Large Entity

Application Type	FILING FEE	SEARCH FEE	EXAMINATION FEE		Fee Paid
Utility	($300)	($500)	($200)	(Total = $1000)	[]
Design	($200)	($100)	($130)	(Total = $430)	[]
Reissue	($300)	($500)	($600)	(Total = $1400)	[]
Provisional filing fee				(Total = $200)	[]

3. APPLICATION SIZE FEE:

Sheets of Spec and Drawings []
($250 for each 50 sheets in excess of 100, except for sequence and program listings)
SUBTOTAL (2)+(3) ($)[]

4. EXTRA CLAIM FEES FOR UTILITY AND REISSUE:

	Extra Claims		Fee from Below		Fee Paid
Total Claims	[] - 20** =	[] x	[]	=	[]
Independent Claims	[] - 3** =	[] x	[]	=	[]
Multiple Dependent claims:			[]	=	[]

** or number previously paid, if greater; For Reissues, see below

Fee Description
Claims in excess of 20 ($50 per claim)
Independent claims in excess of 3 ($200 per claim)
Multiple dependent claim, if not paid ($360)
**Reissue: each independent claim over 3 and more than in the original patent ($200 per claim)
**Reissue claims: each claim over 20 and more than original patent ($50 per claim)

SUBTOTAL (4) ($)[]

FEE CALCULATION (continued)

5. ADDITIONAL FEES

Fee Description		Fee Paid
Extension for reply within 1st month	($120)	[]
Extension for reply within 2nd month	($450)	[]
Extension for reply within 3rd month	($1,020)	[]
Extension for reply within 4th month	($1,590)	[]
Extension for reply within 5th month	($2,160)	[]
Information Disclosure Statement fee	($180)	[]
37 CFR 1.16(f) Late Oath/Declaration (nonprovisional)	($130)	[]
37 CFR 1.17 (q) Surcharge - Late provisional filing fee or cover sheet	($50)	[]
Non-English specification	($130)	[]
Notice of Appeal	($500)	[]
Filing a brief in support of an appeal	($500)	[500]
Request for oral hearing	($1,000)	[]
Acceptance of unintentionally delayed claim for priority under 35 U.S.C. 119, 120, 121, or 365 (a) or (c)	($1,370)	[]
Other: _____		[]

SUBTOTAL(5) ($) [500]

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Juliet A. Jones	Registration No. (Attorney/Agent)	54,202	Telephone	(513) 626-2127
Signature				Date	March 7, 2006

This collection of information is required by 37 CFR 1.17. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P. O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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TO: **Commissioner for Patents - United States Patent and Trademark Office**

Fax No. 571-273-8300 Phone No.

FROM: Paula Durr (Typed or printed name of person signing Certificate)

Fax No. 513-626-1355 Phone No. 513-626-1679

Application No.: 10/090,517

Inventor(s): Resch al.

Filed: March 4, 2002

Docket No.: 8866

Confirmation No.: 6459

FACSIMILE TRANSMITTAL SHEET AND

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. §1.8

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on March 7, 2006, to the above-identified facsimile number.

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1) Fee Transmittal-1 page
2) Appeal Brief-13 pages
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/090,517
Inventor(s)	:	B. S. Resch et al.
Filed	:	March 4, 2002
Art Unit	:	1617
Examiner	:	Shengjun Wang
Docket No.	:	8866
Confirmation No.	:	6459
Customer No.	:	27752
Title	:	Stable Personal Care Compositions Containing a Retinoid

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir,

This Appeal Brief is submitted in support of the Notice of Appeal transmitted to the PTO via facsimile on January 18, 2005, which set a two-month period for response and in response to the Notice of Non-Compliant Appeal Brief dated February 24, 2006, which set a one month period for response.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 1-26 are pending in the present application. Claims 13 and 25 have been withdrawn. Claims 1-12, 14-14 and 26 are appealed. A complete copy of the appealed claims is set forth in the Claims Appendix.

STATUS OF AMENDMENTS

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03/08/2006 HLE333 00000090 162480 10090517
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No amendment was filed.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a topical personal care composition having improved stability of a retinoid, comprising a retinoid; a preservative selected from the group consisting of phenols, phenol salts, quaternium ammonium compounds, halogens, halogen salts, alcohols, inorganic salts, zinc pyrithione, emulsifying preservatives, and mixtures thereof; and a dermatologically acceptable carrier. The composition is substantially free of parahydroxybenzoic acid esters. See specification, page 3, lines 21-28.

The present invention further relates to a topical personal care composition having improved stability of a retinoid, comprising a retinoid selected from the group consisting of retinyl esters, retinyl aldehydes, and mixtures thereof; a preservative; and a dermatologically acceptable carrier. The composition is substantially free of parahydroxybenzoic acid esters, and is substantially free of formaldehyde and formaldehyde donating compounds. See specification, page 3, lines 29-32 through page 4, lines 1-6.

The present invention further relates to a topical personal care composition having improved stability of a retinoid, comprising from about 0.0001% to about 2% of a retinoid (specification, page 6, lines 29-31); an anti-oxidant (specification, page 21, lines 1-4); from about 0.1% to about 0.35% of a preservative selected from the group consisting of carboxylic acid, carboxylic acid salts, and mixtures thereof (specification, page 8, line 20, through page 9, line 4); and a dermatologically acceptable carrier (page 12, lines 17-20). The composition is substantially free of parahydroxybenzoic acid esters and is substantially free of formaldehyde and formaldehyde donating compounds (specification, page 11, line 13 through page 12, line15).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Rejection under 35 U.S.C. 103(a) over U.S. Patent No. 6,024,941 in view of U.S. Patent No. 5,939,082 in further view of U.S. Patent No. 5,821,237.

ARGUMENTS

The Examiner has failed to establish a prima facie case of obviousness, and rejection under 35 U.S.C. 103(a) is therefore improper.

Claims 1-12, 14-14 and 26 have been rejected under 35 U.S.C. 103(a) over U.S. Patent 6,024,941, issued to Yanagida et al. (hereinafter "Yanagida"), in view of U.S. Patent No. 5,939,082, issued to Oblong et al. (hereinafter "Oblong") in further view of U.S. Patent No. 5,821,237 issued to Bissett et al. (hereinafter "Bissett"). The present invention teaches personal care compositions having improved retinoid stability. An important aspect of the present invention is that the compositions are substantially free of parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds, which Applicants have found contribute significantly to the breakdown of retinoids. Parahydroxybenzoic acid esters include, for example, methylparaben, ethylparaben, propylparaben, isopropylparaben and butylparaben.

Yanagida teaches cosmetic compositions comprising vitamin A compounds (retinoids) and stabilizers selected from a number of well-known stabilizers. Oblong teaches the use of vitamin A in cosmetic compositions, and Bissett teaches the use of preservatives used in the instant composition, for example *o*-phenylphenol. The Office Action concludes that it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to make cosmetic compositions containing the vitamin A compound retinyl propionate, without using parahydroxybenzoic acid esters and formaldehyde donating compounds, and which employ *o*-phenylphenol as a preservative.

Applicants appeal this rejection, and respectfully assert that the Examiner has failed to establish any of the criteria required for a *prima facie* case of obviousness. These criteria include a suggestion or motivation to combine the references, a reasonable expectation of success, and a teaching or suggestion of all the claim limitations. *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438.

A. There is no motivation to combine the references, because the cited art fails to suggest the desirability of excluding parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds to improve retinoid stability.

The problem of vitamin A instability has long been recognized. Yanagida states that "it has been difficult to stably formulate vitamin A into an external skin treatment composition." However, nowhere does the cited art recognize specifically that the

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presence of parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds contributes to retinoid instability. Conversely, there is no suggestion that the exclusion of these compounds can significantly increase the stability of these compounds.

"The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re* Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1786 (Fed. Cir. 1992). Yet the Office Action of February 23, 2004, states on page 4, paragraphs 11 and 12:

> Yanagida does not teach to expressly exclude parahydroxybenzoic acid ester[s], or formaldehyde and formaldehyde donating compounds, or [to] employ particular vitamin A derivatives ... or [to] employ [a] particular preservative ... . However, as shows in the claims and the examples, Yanagida et al. do not require the present [sic] of parahydroxybenzoic acid ester[s], or formaldehyde, or its donating compounds.

The Office Action acknowledges, therefore, that the cited art is silent on this issue, and thus fails to suggest the desirability of the modification. In fact, Yanagida, Oblong and Bissett all teach away from the present invention, in that all exemplify the use of parahydroxybenzoic acid esters (methyl- and ethylparaben) in compositions containing retinoids.

Bissett describes compositions which are substantially free of formaldehyde or formaldehyde-donating compounds. However, the purpose is unrelated to increasing retinoid stability, and Bissett therefore also fails to recognize the desirability of the modification. In Bissett, the invention was directed toward stabilization of sulfhydryl compounds (i.e. a highly reactive –SH group). See Bissett, Col. 14, line 67 through Col. 15, line 8. Retinoids contain no sulfhydryl groups. The reactive species in retinoids is oxygen-containing, and the issue is prevention of oxidation. Therefore, one would not be motivated by the teachings of Bissett to exclude formaldehyde and formaldehyde donating compounds to increase retinoid stability.

In light of the foregoing, there is no motivation or suggestion to modify Yanagida based on the teachings of Oblong and Bissett. None of the cited art teaches the desirability of the modification, and all teach away from the present invention. Therefore, Applicants must conclude that only with the benefit of hindsight is there a suggestion of

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the desirability of the modification. This is an impermissible basis for a rejection under 35 U.S.C. 103(a).

B. There is no reasonable expectation of success.

Combining the references would fail to produce compositions that exhibit the retinoid stability of the compositions of the present invention.

> The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000).

Applicants have found that parahydroxybenzoic acid esters, formaldehyde and formaldehyde donating compounds contribute significantly to retinoid instability. All references teach the use of these compounds. Bissett and Oblong fail to address the issue of retinoid stability. Yanagida provides no indication that the compositions exhibit stability comparable to those of the present invention. Applicants therefore could have no reasonable expectation of applying any of the references alone or in combination to successfully produce the compositions of the present invention.

C. The cited art fails to teach or suggest all the claim limitations of the present invention.

Applicants describe personal care compositions with improved retinoid stability, comprising a retinoid; a preservative selected, from among others, phenols; and a dermatologically acceptable carrier; and which are essentially free of parahydroxybenzoic acid esters. As stated above, all of the cited references teach compositions containing parahydroxybenzoic acid esters (methyl- and ethylparaben). Therefore, the combination of references fails to teach or suggest all of the claim limitations.

In summary, Applicants point out that in order to establish a prima facie case of obviousness, the Office Action must establish all three of the criteria set forth in *In re Vaeck*. Applicants respectfully submit that the Office Action fails to establish *any* of these criteria. Applicants further reiterate the premise stated in *In re Bisley*:

> The discovery of a problem calling for an improvement is often a very essential element in an invention correcting such a problem; and though

the problem, once realized, may be solved by use of old and known elements, this does not necessarily negative invention. 197 F.2d 355, 94 USPQ 80, 86-87 (C.C.P.A. 1952).

The Office Action asserts that the claimed invention is obvious "not after [the] 'source of the problem is identified' but before Applicants' claimed invention was made." See Office Action of Sept. 3, 2004, paragraph 7. Applicants assert that in light of the cited art and the arguments presented above, this remedy to the long-standing problem of retinoid instability had not been taught or suggested by the cited art. Only after Applicants accomplished the inventive step of identifying the source of the problem did the remedy become clear. Applicants' invention therefore is non-obvious.

SUMMARY

In light of the arguments set forth above, it is respectfully submitted that the rejection under 35 U.S.C. 103(a) is improper. Applicants respectfully request reversal of the rejection of claims 1-12, 14-14 and 26.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY

Juliet A. Jones
Registration No. 54,202
(513) 626-2127

March 7, 2006
Customer No. 27752

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CLAIMS APPENDIX

1. (Original) A topical personal care composition having improved stability of a retinoid, comprising:

a) a retinoid;

b) a preservative selected from the group consisting of phenols, phenol salts, quaternium ammonium compounds, halogens, halogen salts, alcohols, inorganic salts, zinc pyrithione, emulsifying preservatives, and mixtures thereof; and

c) a dermatologically acceptable carrier;

d) wherein the composition is substantially free of parahydroxybenzoic acid esters.

2. (Original) A topical composition according to Claim 1 wherein the composition comprises from about 0.01% to about 0.5%, by weight of the composition, of the retinoid.

3. (Original) A topical composition according to Claim 1 wherein the retinoid is selected from the group consisting of retinol, retinol esters, retinal, retinoic acid, and mixtures thereof.

4. (Original) A topical composition according to Claim 3 wherein the retinoid is selected from the group consisting of retinyl palmitate, retinyl acetate, retinyl propionate, and mixtures thereof.

5. (Original) A topical composition according to Claim 1 wherein the composition comprises from about 0.001 to about 0.25%, by weight of the composition, of the preservative.

6. (Original) A topical composition according to Claim 1 wherein the preservative is selected from the group consisting of quaternium ammonium compounds, phenols, phenol salts, and mixtures thereof.

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7. (Original) A topical composition according to Claim 1 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, sodium o-phenylphenol, chlorocresol, salicylic acid, salicylic acid salts, chloroxylenol, thymol, triclosan, cresols, benzalkonium chloride, benzethonium chloride, cetylpyridium chloride, sodium dehydroacetate, chlorhexidine, chlorhexidine salts, chloramine T, triclocarban, iodopropynyl butylcarbanate, chlorobutanol, chlorphenesin, hinokitol, silver chloride, zinc pyrithione, alkyldiaminothylglycine hydrochloride, glycerol caprylate, and mixtures thereof.

8. (Original) A topical composition according to Claim 7 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, thymol, benzalkonium chloride, sodium dehydroacetate, chlorhexidine, chlorhexidine gluconate, chloramine T, iodopropynyl butylcarbanate, and mixtures thereof.

9. (Original) A topical composition according to Claim 1 wherein the composition is substantially free of formaldehyde and substantially free of formaldehyde donating materials.

10. (Original) A topical composition according to Claim 1 wherein the composition comprises less than 0.01% of parahydroxybenzoic acid esters.

11. (Original) A topical composition according to Claim 1 wherein the composition further comprises from about 0.01% to about 5% of a preservative enhancer selected from the group consisting of propylene glycol, butylene glycol, EDTA, disodium EDTA, tetrasodium EDTA, and mixtures thereof.

12. (Original) A topical composition according to Claim 1 wherein the composition further comprises a skin care active selected from the group consisting of vitamins, proteins, zeolites, peptides, skin-lightening agents, sunscreen actives, terpene alcohols, desquamation actives, anti-acne actives, anti-wrinkle actives, anti-atrophy actives, anti-

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oxidants, flavanoids, anti-inflammatory agents, anti-cellulite agents, topical anesthetics, tanning actives, skin soothing actives, skin healing actives, conditioning agents, and mixtures thereof

13. (Withdrawn) A method of regulating the condition of skin, said method comprising applying to the skin of a human in need of treatment, a safe and effective amount of a composition according to Claim 1.

14. (Original) A topical personal care composition having improved stability of a retinoid, comprising:

a) a retinoid selected from the group consisting of retinyl esters, retinyl aldehydes, and mixtures thereof;

b) a preservative; and

c) a dermatologically acceptable carrier;

d) wherein the composition is substantially free of parahydroxybenzoic acid esters; and

e) wherein the composition is substantially free of formaldehyde and formaldehyde donating compounds.

15. (Original) A topical composition according to Claim 14 wherein the composition comprises from about 0.01% to about 0.5%, by weight of the composition, of the retinoid.

16. (Original) A topical composition according to Claim 15 wherein the retinoid is selected from the group consisting of retinyl palmitate, retinyl propionate, retinyl acetate, and mixtures thereof.

17. (Original) A topical composition according to Claim 16 wherein the retinoid is retinyl propionate.

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18. (Original) A topical composition according to Claim 14 wherein the composition comprises from about 0.001 to about 0.25%, by weight of the composition, of the preservative.

19. (Original) A topical composition according to Claim 14 wherein the preservative is selected from the group consisting of phenols, phenol salts, carboxylic acids, carboxylic acid salts, quaternium ammonium compounds, halogens, halogen salts, alcohols, inorganic salts, heterocyclic compounds, emulsifying preservatives, and mixtures thereof.

20. (Original) A topical composition according to Claim 19 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, sodium o-phenylphenol, chlorocresol, salicylic acid, sodium salicylate, magnesium salicylate, resorcin, chloroxylenol, thymol, triclosan, cresols, benzalkonium chloride, benzethonium chloride, cetylpyridium chloride, benzoic acid, sodium benzoate, sorbic acid, dehydroacetic acid, sodium dehydroacetate, chlorhexidine, chlorhexidine gluconate, chloramine T, triclocarban, iodopropynyl butylcarbanate, chlorobutanol, chlorphenesin, hinokitol, silver chloride, zinc pyrithione, alkyldiaminothylglycine hydrochloride, glycerol caprylate, and mixtures thereof.

21. (Original) A topical composition according to Claim 20 wherein the preservative is selected from the group consisting of pentylene glycol, o-phenylphenol, thymol, benzalkonium chloride, dehydroacetic acid, sodium dehydroacetate, chlorhexidine, chlorhexidine gluconate, chloramine T, iodopropynyl butylcarbanate, and mixtures thereof.

22. (Original) A topical composition according to Claim 14 wherein the composition comprises less than 0.01% of parahydroxybenzoic acid esters.

23. (Original) A topical composition according to Claim 14 wherein the composition further comprises from about 0.01% to about 5% of a preservative enhancer selected from

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the group consisting of pentylene glycol, butylene glycol, EDTA, disodium EDTA, tetrasodium EDTA, and mixtures thereof.

24. (Original) A topical composition according to Claim 14 wherein the composition further comprises a skin care active selected from the group consisting of vitamins, proteins, zeolites, peptides, skin-lightening agents, sunscreen actives, terpene alcohols, desquamation actives, anti-acne actives, anti-wrinkle actives, anti-atrophy actives, anti-oxidants, flavanoids, anti-inflammatory agents, anti-cellulite agents, topical anesthetics, tanning actives, skin soothing actives, skin healing actives, conditioning agents, and mixtures thereof

25. (Withdrawn) A method of regulating the condition of skin and/or hair, said method comprising applying to the skin and/or hair of a human in need of treatment, a safe and effective amount of a composition according to Claim 14.

26. (Original) A topical personal care composition having improved stability of a retinoid, comprising:

a) from about 0.0001% to about 2% of a retinoid;
b) an anti-oxidant;
c) from about 0.1% to about 0.35% of a preservative selected from the group consisting of carboxylic acid, carboxylic acid salts, and mixtures thereof; and
d) a dermatologically acceptable carrier;
e) wherein the composition is substantially free of parahydroxybenzoic acid esters; and
f) wherein the composition is substantially free of formaldehyde and formaldehyde donating compounds.

EVIDENCE APPENDIX

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RELATED PROCEEDINGS APPENDIX

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